Fisher & Paykel
HEALTHCARE

MAR 0 6 2003

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K022609

31 July, 2002

510(k) Summary of Safety and Effectiveness Information

Model No. / Name: **PW820 Surgical Patient Warmer**
Classification Name: Infrared Lamp - 89 ILY
Physical Medicine Devices, 21 CFR §890.5500 (Class II)

Predicate Device: Fisher & Paykel Healthcare PW810 Patient Warmer, K982636
Classification Name: Infrared Lamp - 89 ILY
Physical Medicine Devices, 21 CFR §890.5500 (Class II)

(a)(1) - (a)(3) (refer to information above and concluding this summary)
(a)(4) Description of the Device

The PW820 Surgical Patient Warmer consists of a heater assembly and controller unit, with mounting pole and base sections. The heater assembly includes a single rod infrared heating element housed inside a parabolic reflector. Two spotlights (designed to set the distance of the heater from the patient) are mounted at the back of the heater assembly. The heater assembly can be swung either side of the warmer, away from the patient, or rotated through ± 90° along the patient axis. A metal grill on the underside of the heater prevents contact with the heating element.

The controller unit supports the heater assembly, and contains the device electronics, control panel and labels. The front panel contains the control buttons, temperature display, main power switch and temperature sensor socket. Controls include temperature selection and positioning spotlight operation. LED displays include indicators for set temperature, alarms, positioning spotlights, heater power, and a 3-digit skin temperature display. The main label is located on the controller rear panel, and the power socket is mounted in the underside of the controller.

A single pole mounting system supports the controller unit, with two sections of stainless steel tubing providing height adjustment. The lower pole section is mounted into a stabilizer weight attached to a five-arm base unit, with castors which include foot-operated brake levers.

Accessories for the PW820 include 'Reusable' and 'Single Use' skin temperature sensor probes, cord tidy, I.V. pole and bag hook.

When switched on, with the desired temperature selected and sensor positioned correctly on the patient, the PW820 provides stable control of skin temperature by automatically adjusting the heater power to compensate for varying metabolic and environmental conditions. Audible and visual alarms alert the user to high/low temperature situations, faults and power failure. Independent safety features are included to control maximum output and avoid thermal injury to the patient.

(a)(5) Statement of the Intended Use

The Fisher & Paykel Healthcare PW820 device is an Infra-red Lamp, as per 21 CFR §890.5500. It emits energy at infra-red frequencies to provide topical heating, and is used to provide thermal support for anesthetized patients (who are susceptible to undesirable heat loss) undergoing surgical treatment. Additionally, the PW820 may also be used to provide topical heating in other clinical situations where unobstructive external thermal support for patients is required (for example, post-operative recovery, hypothermia recovery).

(a)(6) Technological Characteristics Summary

The PW820 is derived from the PW810 Patient Warmer. Changes incorporated into the PW820 consist of converging twin LED spotlights for determination of heater-to-patient distance, a closer heater-to-patient distance, adjustable heater angle via a swivel joint, a shorter base stem, minor software changes and modified labeling and operating instructions. These changes do not affect substantial equivalence to the PW810. The overall design, materials, energy source and performance of the PW820 are the same as the PW810.

(b)(1) Discussion of the Non-Clinical Tests

The PW820 has been fully tested to the IEC 60601-1 and IEC 60601-1-2 medical electrical and EMC standards. The device meets the requirements of the standards, and the deviations relevant to the USA in UL 2601-1. The safety and effectiveness of the height positioning LED spotlight system has also been tested.

(b)(2) Discussion of the Clinical Tests

A randomized, controlled trial compared the efficacy of the PW820 with that of a forced air warming blanket in providing intra-operative warming for patients undergoing laparoscopic cholecystectomy surgery. The results showed that the PW820 was at least as effective as the warming blanket in maintaining patient temperature during both surgery and the recovery period.

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the PW820 Patient Warmer indicates that it meets design and performance functional requirements. Clinical verification studies demonstrate the successful use of the warmer and its ability to provide safe effective patient warming. The proposed device meets the requirements of international and US medical electrical equipment standards for safety.

signed: Robert Petry date: 31 July 2002

Robert Petry
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 6 2003

Mr. Robert Petry
Regulatory Affairs Engineer
Fisher & Paykel Healthcare Limited
15 Maurice Paykel Place, East Tamaki
P.O. Box 14 348, Panmure
Auckland, New Zealand

Re: K022609
Trade/Device Name: Surgical Patient Warmer PW820 JHU
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: December 3, 2002
Received: December 6, 2002

Dear Mr. Petry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

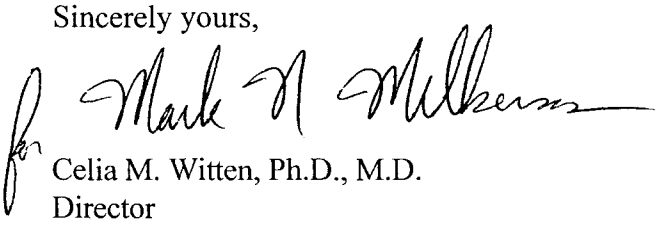
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification [510(k)] Number: K022609

3 March 2003

Fisher & Paykel Healthcare PW820 Surgical Patient Warmer

PREMARKET NOTIFICATION 510(k)
INDICATIONS FOR USE STATEMENT

The Fisher & Paykel Healthcare PW820 Surgical Patient Warmer is an Infra-red lamp. It emits energy at infra-red frequencies to provide topical heating. The PW820 is intended primarily for use in the operating room in order to alleviate patient body-core cooling induced by the use of anesthetic drugs and the operating room environment. Additionally, the PW820 may also be used to provide topical heating in other clinical situations where unobstructive external thermal support for patients is required (for example, post-operative recovery, hypothermia recovery, ICU).

The PW820 is operated at a fixed skin surface temperature setting of either 41°C or 37°C. The setting of 41°C is intended for adult patients under general anesthetic. The setting of 37°C is intended for pediatric and infant patients and for non-anesthetised adults.

The PW820 is for use with infants only during surgery.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR §801.109)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022609